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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,876	05/04/2007	Claudia Lemmel	2912919-006000	2541
84331 7590 12/22/2009 Baker Donelson Bearman, Caldwell & Berkowitz, PC 555 Eleventh Street, NW, Sixth Floor Washington, DC 20004				
EXAMINER				
YU, MISOOK				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
12/22/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/587,876

**Applicant(s)**

LEMMEL ET AL.

**Examiner**

MISOOK YU

**Art Unit**

1642

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-61 is/are pending in the application.
- 4a) Of the above claim(s) 50-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-49 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)
- Paper No(s)/Mail Date 10/13/2009, 11/15/2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I in the reply filed on 10/21/2009 is acknowledged.

Claims 50-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2009.

New claim 60 is drawn to a method different from the elected group I, because the active steps in group I use stable isotopes and chemical modification of the peptides being isolated while new claim 60 does not use stable isotopes and chemical modification. Accordingly, claim 60 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 41-61 are pending. Claims 41-49 and 61 are examined on merits.

### ***Priority***

Applicant cannot rely upon the foreign priority papers to overcome the rejection under 35 U.S.C. 102(a) below because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 41-49 and 61 are rejected under 35 U.S.C. 102(a) as being anticipated by Lemmel et al., IDS, Nature Biotechnology, vol. 22, pages 450-545.

Claims 41-49 and 61 are drawn to method of identifying tumor associated peptides (MHC bound in claim 48) comprising isolating peptides from tumor sample and corresponding healthy control sample, labeling the peptides with stable isotopes followed by determining the ratio of peptides in the two samples.

Lemmel et al., teaches a method of identifying tumor associated MHC ligands by mass spectrometry using stable isotope labeling.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41-47 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moritz et al., IDS filed on 11/15/2006, Proteomics (2003) vol. 3, pages 2208-2220.

Claims are drawn to method of identifying and quantifying tumor-associated peptides comprising isolating peptides from tumor tissue and healthy control, labeling the peptide with stable isotopes, chemically modifying the labeled peptides, mixing the peptides, followed by separating, identifying the amino acid sequence, and quantifying relative ratio of peptides from tumor vs. normal tissue, wherein claim 42 and 44 further limit the stable isotopes of the base claim to be to deuterium and hydrogen, and claim 43 further limit the chemical modification of the base claims to be guanidination and nicotinylation, while claims 46 and 47 use HPLC and mass spectrometry (MS), respectively for separating, identifying the amino acid sequence, and quantifying relative ratio of peptides from tumor vs. normal tissue.

Moritz et al., teaches many different methods of quantifying protein abundance ratios between two states such as diseased (one of them, cancer) or healthy tissues, which include a method involving stable isotope labeling with (13)C, (15)N, (18)O or deuterium in combination with mass spectrometry (MS) and HPLC. Note abstract and pages 2215-2217.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success since how to isolate peptides from a tumor tissue and a corresponding tissue as well as stable isotope labeling with (13)C, (15)N, (18)O or deuterium of the isolated peptides in combination with mass spectrometry and HPLC had been known in the art before the effective filing date of the instant application

One of ordinary skill in the art would have been motivated to arrive at the claimed invention because Moritz et al., note the abstract) teaches the isolated peptide(s) could be used "for development of new drug targets to fight against diseases".

### ***Conclusion***

Claims 48 and 49 are not included in the rejection above under 35 U.S.C. 103(a) because combination of use of an antibody binding to HLA class I molecules with stable isotope labeling and chemical modification is not taught or suggested in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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